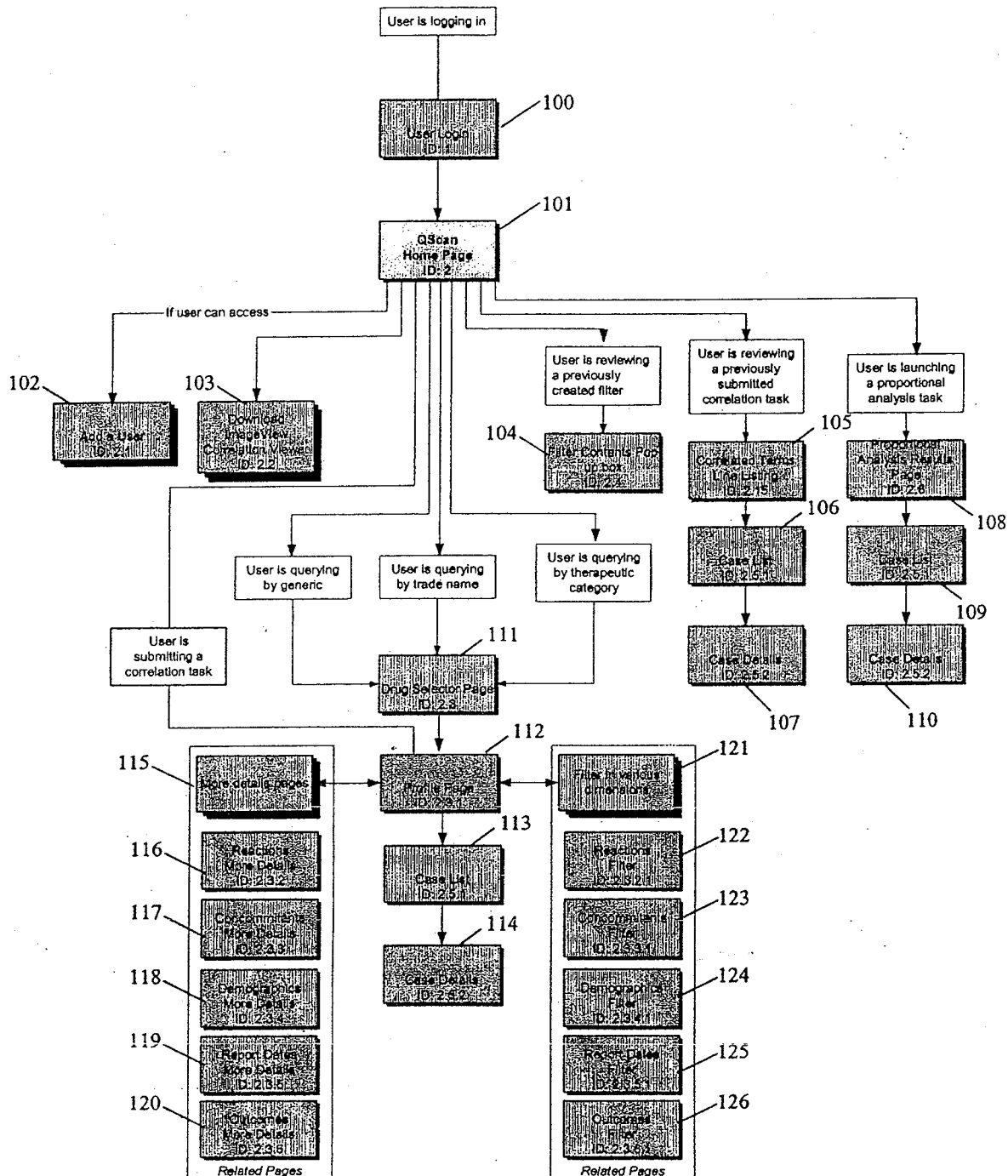


Figure 1



**Figure 2**

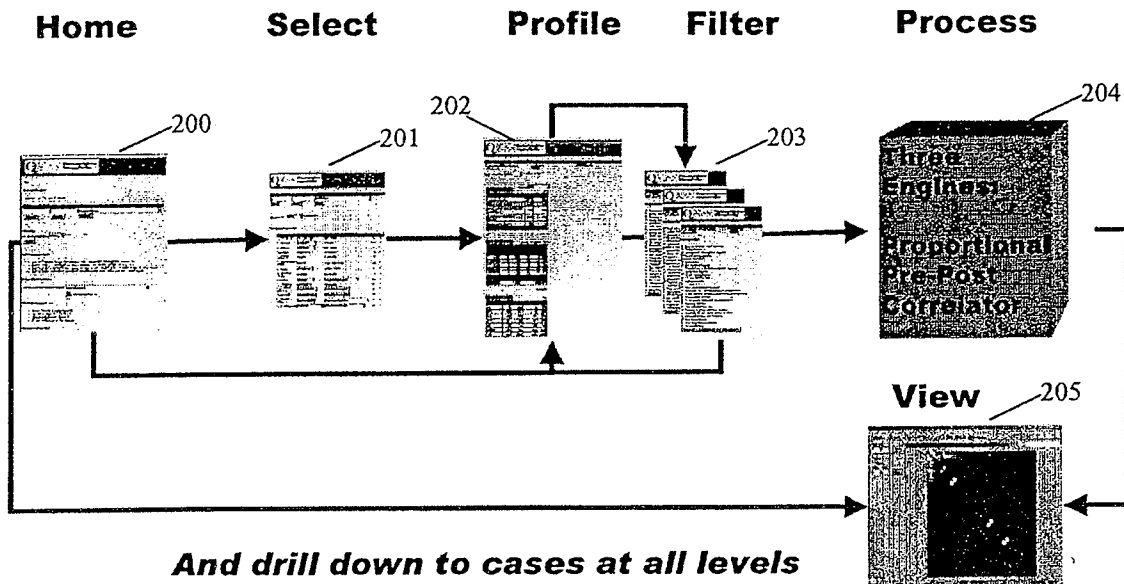


Figure 3

**QSCAN Pharmacovigilance Selector/Profiler**

home 301

Selection/Profiler: Data source: FDA SRS/AERS Combined Data

Generic Name: Trade Name: Therapeutic category:

Search Search Search

302

Filtering:

Saved filter: Select View Apply

303

AEM Engine notices:

- [delete] [Dec 22, 2000 8:41:42 PM] Completed correlation task #15: AMLODIPINE BESYLATE view results...
- [delete] [Dec 22, 2000 6:25:17 PM] Completed correlation task #14: CANDESARTAN CILEXETIL view results...

304

Proportional analyses:

Compute for therapeutic category: Ace Inhibitors

Go ☒ Bayesian filtering ☐ Compare only with therapeutic category

Administrative tasks:

- Add New User
- Log out
- Download the ImageView 1.1.4: Correlation viewer (1.3 MB)

Figure 4

Filtering:  
 Saved filter: **Filter 2**

AEM Engine notices:  
 • [delete] [Dec 22, 2000 6:41:42 PM] Cor  
 • [delete] [Dec 22, 2000 6:26:17 PM] Cor

Proportional analyses:  
 Compute for therapeutic category:   ☒ Bu

**Filter Details - Marshall Therapeutics**

**Current filter: Filter 2**

Drug: CANDESARTAN CILEXETIL

Reactions:

80Cs: Included:

Concomitant Drugs: off

Demographics: Brackets:

Report Dates: off

Outcomes: Included

Figure 5

home > drug selector

Selector/Profiler:

Data source: FDA-SRS/AERS Combined Data

Generic Name:  Trade Name:  Therapeutic category:

Filtering:  
 Saved filter:

22 drugs in category: ACE INHIBITORS:

Generic Name	Trade Names	Therapeutic Categories	Pedigree
AMILORIDE HYDROCHLORIDE	AMILORIDE	Ace Inhibitors	?
AMLODIPINE BESYLATE	AMIODIPINE	Ace Inhibitors	?
BENAZEPRIL HYDROCHLORIDE	BENAZEPRIL	Ace Inhibitors	?
CANDESARTAN CILEXETIL	ATACAND	Ace Inhibitors	?
CAPTOPRIL	ACE-HEMMER	Ace Inhibitors	?
ENALAPRIL MALEATE	ACETENSIL	Ace Inhibitors	?

Figure 6

Map To	Verbatim	Source	Incidents	Case Count	QEDRx Processing	Cross-reference	First/Last Reported Reactions
PROZAC	PROZAC	SRS	47953	47937		Orange Book	Apr 27 1969/Dec 2 1997
PROZAC	Prozac	AERS	3378	3308	S	Orange Book	Nov 1 1997/Jun 29 1999
FLUOXETINE	FLUOXETINE HYDROCHLORIDE	SRS	2204	2203		ND CD Tradename	Jan 1 1979/Oct 14 1997
FLUOXETINE	Fluoxetine	AERS	574	571	S	ND CD Tradename	Nov 1 1997/Jun 18 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	379	378		M Orange Book	Nov 1 1997/Jun 12 1999
PROZAC	Prozac (Fluoxetine)	AERS	140	140		M Orange Book	Nov 7 1997/Apr 24 1999
FLUOXETINE	Fluoxetine Hydrochloride	AERS	122	122	S	Orange Book	Nov 14 1997/Jun 27 1999
FLUOXETINE	Fluoxetine (Fluoxetine Hydrochloride)	AERS	65	65		M Orange Book	Mar 1 1998/Jun 24 1999
FLUOXETINE	Fluoxetine Hcl	AERS	34	34		Orange Book	Nov 1 1997/Nov 1 1998
PROZAC	Prozac (Fluoxetine Hcl)	AERS	20	20		M Orange Book	Nov 1 1997/Mar 12 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	17	17		M Orange Book	
FLUOXETINE	Fluoxetine (Fluoxetine)	AERS	15	15		M Orange Book	Nov 15 1997/Jun 6 1999

Figure 7

700

701

702

703

704

more details...

Reactions		
View: HLT (256 of 1495) filter		
Top 10 HLTs of 256	Reaction Count	% of Reactions
Hypertension and increased blood pressure NEC	68	3.88%
General symptoms and signs NEC	57	3.25%
Disturbances in consciousness	52	2.97%
Renal function analyses	46	2.63%
Headaches NEC	46	2.63%
Cardiac function diagnostic procedures	46	2.63%
Neurological signs and symptoms NEC	45	2.57%
Nausea and vomiting (all forms)	43	2.45%
Asthenic conditions	43	2.45%
Vascular tests NEC including blood pressure	42	2.40%
	<b>Top 10 HLTs</b>	<b>Total reactions</b>
	488	1752

Figure 8

801

802

filter

Concomitant Drugs		Non-Suspect suspect					
Top 10 drugs	S	NS	S	NS	Total	%	
HYDROCHLOROTHIAZIDE	9	36	0	0	45	10.79%	
ASPIRIN	2	38	0	5	45	10.79%	
FUROSEMIDE	2	32	0	1	35	8.39%	
DIGOXIN	0	30	0	0	30	7.19%	
AMLODIPINE BESYLATE	0	24	4	0	28	6.71%	
ENALAPRIL MALEATE	4	15	0	5	24	5.76%	
VERAPAMIL HYDROCHLORIDE	11	10	0	2	23	5.52%	
ESTROGENS CONJUGATED	0	23	0	0	23	5.52%	
METOPROLOL SUCCINATE	8	11	0	3	22	5.28%	
METOPROLOL TARTRATE	0	15	0	7	22	5.28%	
		Non-Suspect suspect					
		Total		Total		Total	
		172		1141		1313	

more details...

Figure 9

900

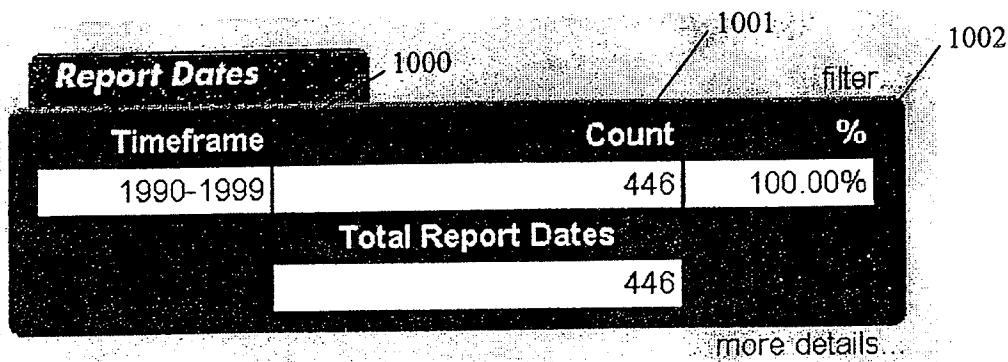
901

filter

Demographics					
Age Group	Male	Female	Unknown	Total	%
>75	18	73	0	91	21.82%
51-75	89	123	1	213	51.08%
31-50	30	16	0	46	11.03%
16-30	2	1	0	3	0.72%
<16	0	0	0	0	0.00%
Unknown	11	30	23	64	15.35%
Total	150	243	24	417	
%	35.97%	58.27%	5.76%		

more details

**Figure 10**



**Figure 11**

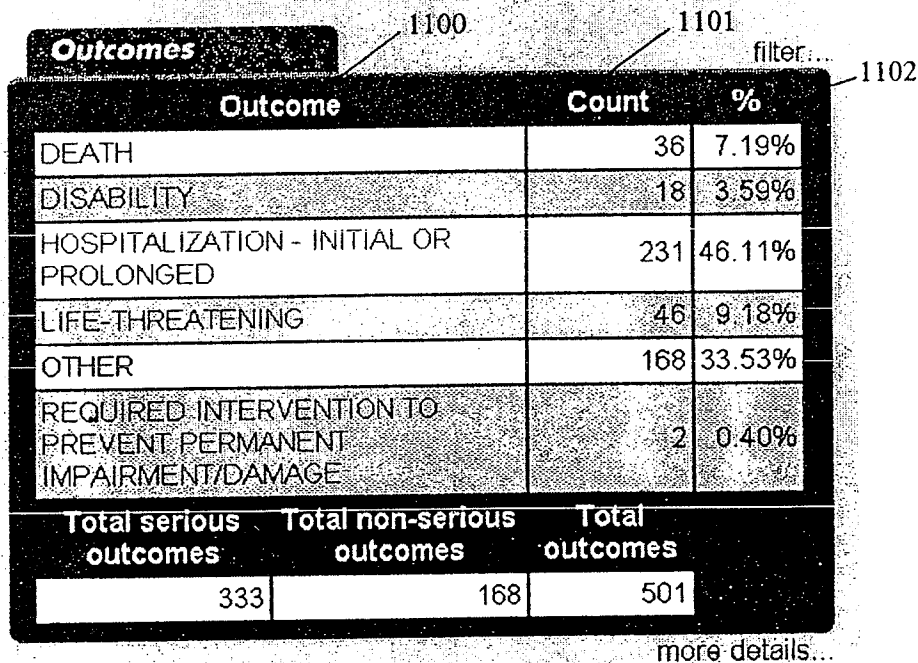




Figure 12

✓ Reactions | Drugs | Outcomes | Report Sources | Timeframes | Demographics | Cases | Filter Notes

deafness **Filter**

☒ Reactions

- ☒ blood and lymphatic system disorders
- ☒ cardiac disorders
- ☒ congenital and familial/genetic disorders
- ☒ ear and labyrinth disorders
  - ☒ external ear disorders (exc congenital)
  - ☒ hearing disorders
    - ☒ deafness and hyperacusis
      - ☒ deafness: conductive (exc otosclerosis)
      - ☐ deafness: neurosensory
      - ☐ deafness: permanent
      - ☐ deafness: transitory
      - ☒ dysacusis
      - ☒ hearing impaired
      - ☐ hearing impairment aggravated
      - ☐ hyperacusis
      - ☒ hypoacusis
      - ☐ presbycusis
- ☒ inner ear and eighth cranial nerve disorders
- ☒ middle ear disorders (exc congenital)
- ☒ miscellaneous ear disorders

- ☒ endocrine disorders
- ☒ eye disorders
- ☒ gastrointestinal disorders

**Apply** Generate profile for this filter (This Filter has not been profiled) **Save**

Figure 13

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL (Task 95). View with ImageView

1303 1304 1300 1305 1302 1306

Correlated Terms					
[Rank]	[Score]	[Term 1]	[Category]	[Term 2]	[Category]
1	7706	Female	Sex	CANDESARTAN CILEXETIL	Target Drug
2	7661	Renal function analyses	Other Reaction	Renal failure and impairment	Other Reaction
3	7244	Paralysis (exc congenital and cranial nerve)	Other Reaction	Central nervous system haemorrhages and cerebrovascular accidents	Other Reaction
4	6901	HOS	Outcome	CANDESARTAN CILEXETIL	Target Drug
5	6888	TRIAMTERENE	Other Drug	DICLOFENAC SODIUM	Other Drug
6	6286	OTH	Outcome	CANDESARTAN CILEXETIL	Target Drug
7	5868	Sex Not Specified	Sex	Age Not Specified	Age
8	5773	VERAPAMIL	Other Drug	TRIAMTERENE	Other Drug
9	5765	HOS	Outcome	Female	Sex
10	5753	Male	Sex	CANDESARTAN CILEXETIL	Target Drug

Figure 14

## Correlation Details

Analyzed Drug: CANDESARTAN CILEXETIL

Cases for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

1401 1402 1403 1404 1405 1406 1407 1408

Cases 1 to 18 of 18 cases

	Case ID	Sex	Manufacturer Control Code	FDA Report Receipt Date	Age	Drugs	Reactions	Serious
1	3263641	F	19990300088	1999-06-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N
2	3196047	F	19990200143	1999-03-12	57	Acuretic, Atorvastatin, Atacand, Cefixime, Nitro-Dur, Terbasmin, Expectorante	Blood Creatinine Increased; Blood Urea Increased; Hypotension NOS; Renal Failure Acute	Y
3	3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Claritin, Antivert, Pyridium, Zolof, Dyazide, Verapamil - Slow Release, Ambien	Abdominal Pain Nos; Blood Creatinine Increased; Blood Urea Increased; Coronary Artery Disease Nos; Haemoptysis; Heart Rate Increased; Hypertension Aggravated; Renal Failure Acute	N
4	3270258	F	19990400499	1999-06-26	75	Atacand, Hydrochlorothiazide	Atrioventricular Block Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram ST Segment Depression; Electrocardiogram U Wave Appearance; Electrolyte Imbalance; Hypochloreaemia; Hypokalaemia; Hyponatraemia; Loss Of Consciousness Nec; Renal Impairment Nos; Syncope	N

# Figure 15

## Correlation Details:

Analyzed Drug: CANDESARTAN CILEXETIL

Case for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

1501	Case ID:	3198047				
1502	Sex:	F				
1503	Age:	57.0 years, 0.0 months				
1504	Reactions:	As Reported	Preferred Term	High Level Term	High Level Group Term	System Organ Class
		Blood Creatinine Increased	Blood Creatinine Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Blood Urea Increased	Blood Urea Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Hypotension NOS	Hypotension NOS	Hypotension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders
		Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (exc nephropathies)	Renal and urinary disorders
1505	Concomitant Drugs:	Name	Dose	Route	Suspect Status	
		Acuretic	TAB QD		Yes	
		Atorvastatin			No	
		Atacand	16 MG QD PO ORAL		Yes	
		Cefixime			No	
		Nitro-Dur			No	
		Terbesmin Expectorante			No	
1506	Outcomes:	HOSPITALIZATION - INITIAL OR PROLONGED (HO) LIFE-THREATENING(LT)				
1507	Manufacturer Control Code:	19990200143				
1508	Manufacturer Date:	1999-03-5				
1509	Adverse Event Date:	1998-12-13				
1510	Report Type:	EXP				
1511	Report Source:	OTH				
1512	Case Source:	AERS				
1513	Narrative:					

# Figure 16

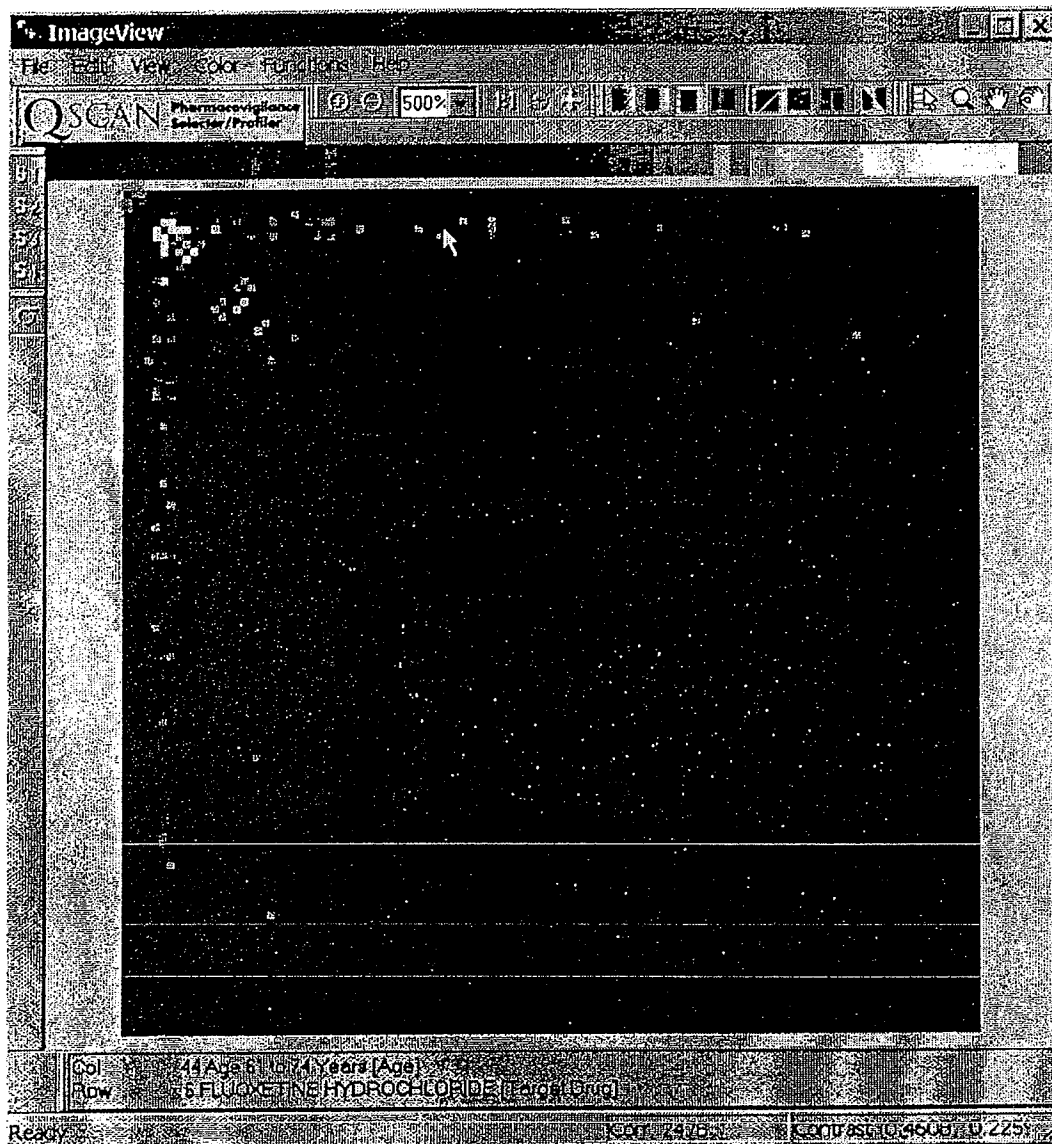
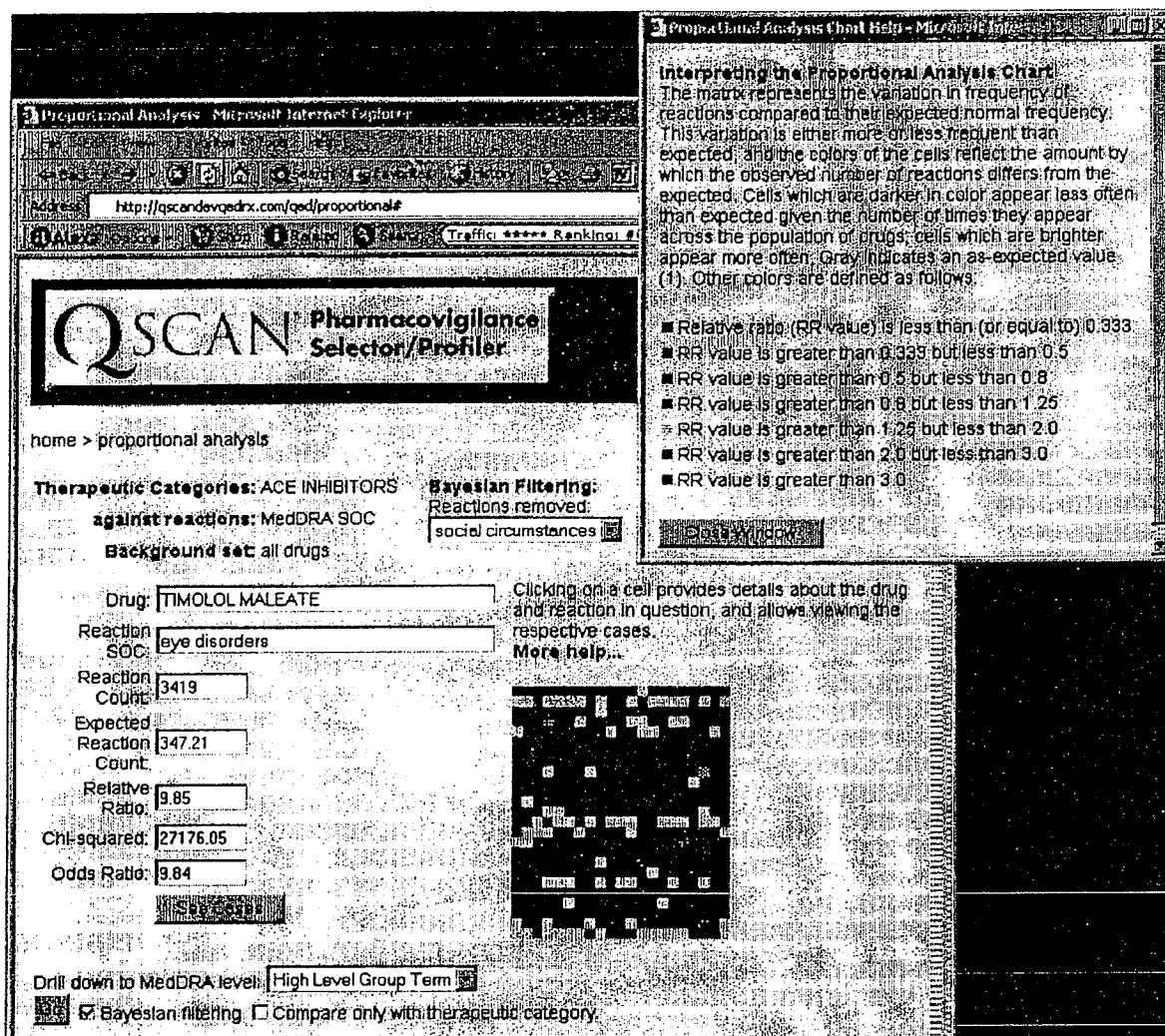
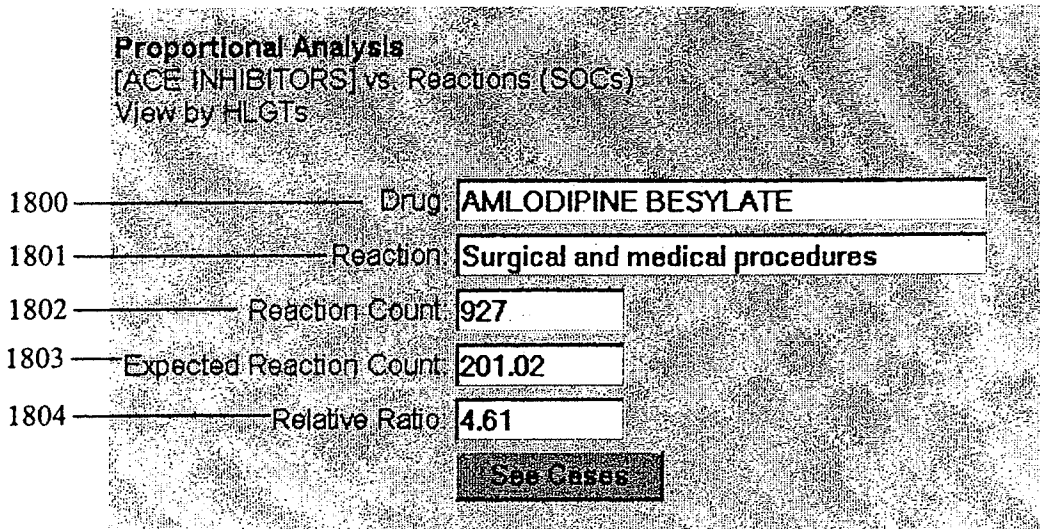


Figure 17



# Figure 18



# Figure 19

550 entries for this analysis are displayed below.

Correlated Terms		1900	1901	1902	1903	1904
[Reaction]	[Drug]	[Count]	[Expected Count]	[Relative Ratio]		
1 6: Eye disorders	19: TIMOLOL MALEATE	3392	346.3	9.8		
2 24: Surgical and medical procedures	2: AMLODIPINE BESYLATE	1732	200.4	8.6		
3 14: Metabolism and nutrition disorders	1: AMILORIDE HYDROCHLORIDE	838	266.5	3.1		
4 24: Surgical and medical procedures	13: METHYLDOPA	37	15.6	2.4		
5 16: Neoplasms benign and malignant (including cysts and polyps)	17: RESERPINE	65	28.6	2.3		
6 4: Ear and labyrinth disorders	4: CANDESARTAN CILEXETIL	32	14.3	2.2		
7 24: Surgical and medical procedures	20: TRANDOLAPRIL	13	6	2.2		
8 14: Metabolism and nutrition disorders	18: SPIRONOLACTONE	1330	616.1	2.2		

Figure 20

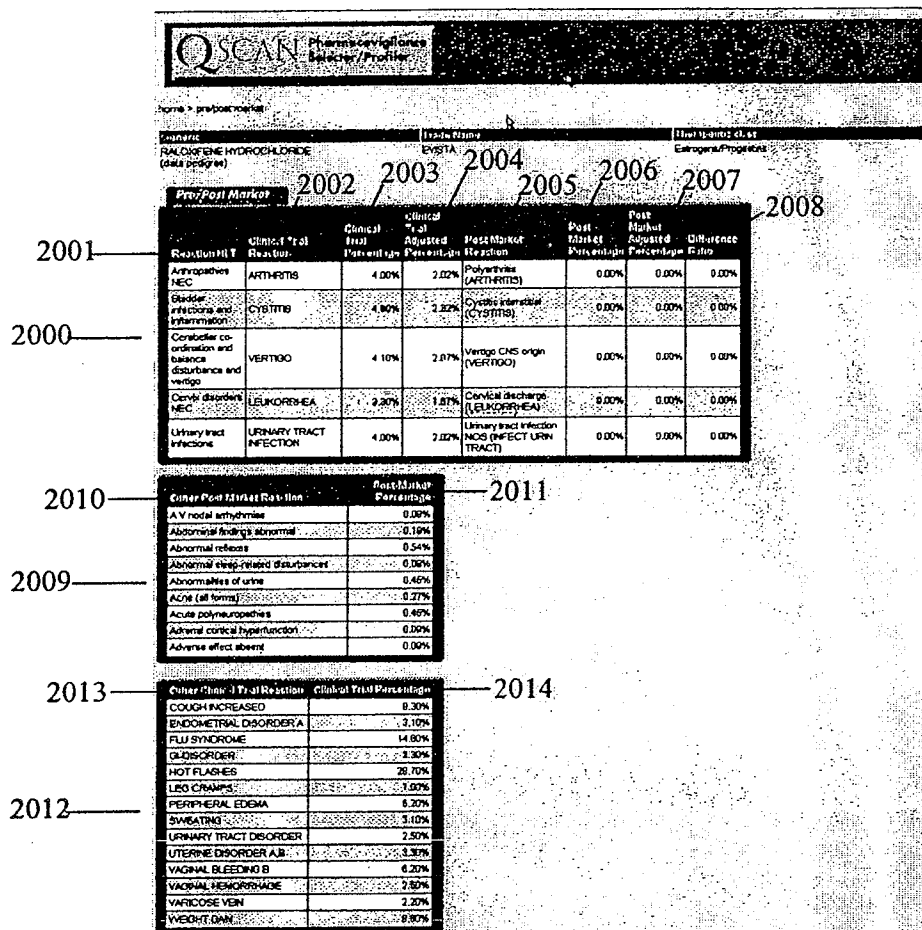


Figure 21

home > drug selector > drug profile > case list

Drug: BENAZEPRIL HYDROCHLORIDE  
Reactions: SOCs: ☒ Included  
Concomitant Drugs: ☐ Off  
Demographics: ☐ Off  
Report Dates: ☐ Off  
Outcomes: ☐ Off

Summary view... Cases 1 to 50 of 268 cases  
6 pages  
1 51 101 151 201 251 2101 2102 2103 2104 2105 2106 2107

	[Case ID]	[Sex]	[Manufacturer Control Code]	[DA Report Receipt Date]	[Age]	[Drugs]	[Reactions]	[Serious]
2100	1 3510123	F	2000101748BE	2000-06-1		Tylenol, Albuterol, Duralase G Pm, Aspirin, Asulfamethoxo Ex Bid, Astalin, Lotensin, Zytac, Dcelebrex, Benadryl, Premarin, Lasix, Hclz 25 Mg, Hydrocodone, Immune Globulin Intravenous (Human), Gamimune N 10% - Placebo, Iodine, Xylocaine, Claritin, Glucophage, Methylprednisolone, Nasonex, Singulair, Pntosec, Oxygen, Paxil, Solumedrol Pack, Rezulin 200 Mg Am	Cardiac Murmur Nos; Dyspepsia; Dyspnea Nos; Oedema Lower Limb; Pain In Limb; Phlebitis Nos; Physical Examination Nos Abnormal; Rhinorrhoea; Tenderness Nos; Venous Thrombosis Deep Limb	Y
	2. C01979033	F	97USA10051	1997-08-8		LOTENSIN	Hypertension NOS; Tablet In stool	N
	3 3204366	F	99061673	1998-08-26		Aspirin Coated, Lotensin, Niaspan	Asthenia, Dizziness (Exc Vertigo), Dyspepsia, Flushing, Pain Nos	Y
	4. C01456473	F	933544001	1984-05-28		LOTENSIN	Nausea; Vasodilatation	N